**REMARKS**

Review and reconsideration of the Office Action dated December 15, 2004, is respectfully requested in view of the above amendments and the following remarks.

Applicants are pleased to see that the Examiner finally understands that the previously cited references do not anticipate or render obvious the present invention. The Examiner has withdrawn all his previous rejections in view of the Stoianovici et al. reference and the Wojciechowicz references.

**The Examiner is respectfully requested to contact the undersigned so that a telephonic interview may be arranged prior to the issuance of any further Office Action.**

Claim 28 has been amended to correct a typographical error. Care has been taken to ensure that no new matter has been added to the claims.

**Applicants respectfully request that the Examiner re-considered the finality of the outstanding Office Action. Reasons are as follows:**

1) the Examiner cited new prior art that was not cited before; **and**

2) a second or any subsequent action on the merits in any application or patent involved in examination proceedings **should not be made final** if it includes a rejection, on prior art **not of record**, of any claim amended to include limitations which should **reasonably have been expected to be claimed.**

In the instant case, Claims 27, 34, 38, and 41 were amended by including the limitation "wherein the cannula is unipolar" and

deleting from the preamble the limitation "continuously conductive unipolar". **The added limitation should reasonably have been expected to be claimed because one of the main arguments against the cited references was that the cannulas of the references were not unipolar.** Applicants believe that the limitation of the cannula being unipolar was not considered by the Examiner previously because the limitation was in the preamble.

**Thus, the Examiner should be expending the previously presented amendment to the claims.**

**IN VIEW OF THE ABOVE, THE FINALITY OF THE OFFICE ACTION IS IMPROPER.**

Applicants believe that the claims are novel in view of the new cited reference.

Applicants note that compared with Claims 27, 34, 38, 41, and 42 the reference fails to teach: 1) a flexible catheter passing through a conductive hollow tube ; 2) a conductive rigid **hollow** tube having **a sharp end;** 3) the **catheter is passed through the conductive rigid hollow tube** (10) formed by a steel tube; 4) the body part including an inlet opening (32, 34) axially aligned with the hollow tube (10) adapted for guiding the catheter **for introduction into the proximal end of the hollow tube** (10), and 5) the electrical connector that **extends through the body part (18) to the outer surface of the hollow tube (10).**

**Compared with Claim 34, the reference further fails to teach** that the distal tip (14) of the cannula tube (10) is a facet cut (12).

Compared with Claims 41 and 42, the reference further fails to teach the body part (18) including **a funnel shaped inlet opening (32, 34) axially aligned with the hollow tube (10) to insert the catheter into the proximal end of the hollow tube.**

**The Present Invention**

The present invention is concerned with the task of providing a **unipolar cannula** for continuous anesthesia, which through simple construction and simple operation unites:

(a) the ability to place a catheter,

(b) the ability to administer anesthetic,

(c) no need for separate electrical conductors to supply electricity for electro-stimulation to the tip of the catheter, since the body of the catheter is used as a conductor, and

(d) the advantage of very precise electro-stimulation.

Where it was previously necessary to, e.g., simultaneously introduce a hose for anesthetic and a separate unipolar canula into a plastic cannula tube, the inventive unipolar **cannula** can be placed or located with the help of electrical nerve stimulation. The outer insulating covering of the cannula tube, which leaves only a very small, almost pinpoint area of the tip free, makes possible an extraordinarily precise placement of the tip. The unipolar **cannula** can itself be used for the guided introduction of the **catheter**. The connection for electro-stimulation is introduced through the side of the body part and contacts the outside of the electrically conductive cannula tube. This manner of connection does not impede or constrict therewith

the axial inlet opening of the body part. After the placement of the unipolar cannula with the help of electro-stimulation, the catheter can be introduced through the cannula tube, without any requirement that the position of the unipolar cannula must be changed or other measures be taken.

Preferably, a releasable or removable connection is formed with the body part at the introduction opening, preferably a Luer-lock connection (Claim 32). At this connection, an injection hose can be connected, if desired, for injection of an initial or a short duration anesthetic. Likewise, a needle can be connected to the releasable connection, for injection of an anesthetic or also for fluids for aspiration for position control.

The possibility of using the body part both for the alternative connection of an injection hose or a needle as well as for introduction of the catheter makes the unipolar cannula extremely versatile. This versatility is achieved using an extremely simple and economical design. The manipulation of the unipolar cannula is likewise extremely simple, since the cannula can be employed without changing the position both for the injection or aspiration as well as for the introduction of the catheter. The axially aligned connection of a needle at the proximal body part makes possible also the carrying out of the nerve block with a one-hand technique.

**Paragraph 1 (Obviousness)**

The Examiner rejects Claims 27, 30-35, 38-39, and 41-42 under 35 U.S.C. 103(a) as obvious over Krebs (US Pat. No. 4,776,847).

The position of the Examiner can be found on pages 2-5 of the Office Action.

Applicants respectfully traverse.

Applicants note that the present set of claims includes five independent claims, namely claims 27, 34, 38, 41, and 42.

**The following remarks are addressed to the rejected independent claims 27, 34, 38, 41, and 42, because, if these claims are not obvious, it follows that none of the other rejected dependent claims are obvious.**

Applicants note that compared with Claims 27, 34, 38, 41, and 42 the reference fails to teach: 1) a flexible catheter passing through a conductive hollow tube ; 2) a conductive rigid **hollow** tube having **a sharp end;** 3) the **catheter is passed through the conductive rigid hollow tube** (10) formed by a steel tube; 4) the body part including an inlet opening (32, 34) axially aligned with the hollow tube (10) adapted for guiding the catheter f**or introduction into the proximal end of the hollow tube** (10), and 5) the electrical connector that **extends through the body part (18) to the outer surface of the hollow tube (10).**

**Compared with Claim 34, the reference further fails to teach** that the distal tip (14) of the cannula tube (10) is a facet cut (12).

Compared with Claims 41 and 42, the reference further fails to teach the body part (18) including **a funnel shaped inlet**

**opening (32, 34) axially aligned with the hollow tube (10) to insert the catheter into the proximal end of the hollow tube.**

**Regarding point 1**

Applicants note that on column 3, lines 29-36, there is an indication that:

"After the perforation of the vasometer nerve sheath by the puncturing tip of the steel mandrel, the plastic tube is advanced in a known manner on the steel mandrel and brought into the desired position where it is to remain. **The steel mandrel is then retracted from the plastic tube**. The exactly positioned plastic tube can then be used for the injection of an anesthetic or as guiding tube for a flexible catheter that is to be inserted."

Thus, the catheter does not pass through the conductive hollow tube (**the conductive tube is solid**- Column 2, lines 16-20); but, rather from a plastic (**non-conductive**) hollow tube.

Contrary to Krebs in the present invention there is only one hollow steel cannula. This steel cannula is on its outer surface electrically insulated by a plastic covering. So the steel cannula can be used for puncturing as well as for the positioning by electro-stimulation.

After positioning of the steel cannula, the cannula remains in the nerve sheath and the catheter is introduced through this cannula into the nerve sheath.

**Regarding point 2**

The reference teaches a **solid rod** having a puncturing tip **without facets and cutting edges**. (Column 2, lines 16-20). Nowhere in the reference can be found the teaching that the steel

mandrel is hollow.

Furthermore, Applicants notes that the reference is teaching away from using a hollow steel tube (see column 2, lines 25-30) where it is an indication that:

"**In contrast to the known combination needle**, the combination needle according to the invention **has a solid, rod-shaped, rather than hollow, steel mandrel puncturing tip** which has with a level, elliptical partially ground surface without facets and cutting edges forming an angle of at least 45° with the axis, or a conical mantel area with a cone angle of at least 60°, **and is thus relatively blunt**."

Thus, the steel tube of the reference is solid (ours is hollow) and has a blunt end (ours has a sharp end). Furthermore, the reference is teaching away from using a hollow steel tube. See "In contrast to the known …."

Applicants would like to point out to the Examiner that it is the needle and not the steel tube the one that includes the sharp tip. (Column 1, lines 50-55).

**Regarding point 3**

Applicants note that Claim 27 requires that the c**atheter is passed through the conductive rigid hollow tube** (10) formed by a steel tube. The steel tube is in the outside of the device.

Applicants note that in the reference the mandrel (steel tube) is inserted into the plastic tube. The steel tube is in the inside of the system. (Abstract and column 1, lines 14-19)

**Regarding point 4**

In the reference the electric stimulation of a nerve is effected by the hollow or solid steel mandrel. After positioning of the outer plastic tube by electro-stimulation the mandrel is retracted and the plastic tube remains in its position in the nerve sheath and the catheter is introduced through the plastic tube into the nerve sheath.

In Krebs there is a plastic tube which is introduced and positioned in the body of the patient by means of an electrically conductive mandrel. The catheter is introduced through the plastic tube after the electrically conductive mandrel is removed. According to the present invention the same steel tube is used for puncturing the tissue of the patient, for positioning the cannula by electro-stimulation and for introducing the catheter.

This is a major structural difference between the present invention and the cited reference. In addition, Applicants note that the Krebs reference is teaching away from using a **hollow** steel tube; thus, there is not a technological motivation to modify the Krebs reference by providing a hollow steel tube.

In addition, having the conductive tube in the outside end of the cannula is different from having the conductive tube in the inside.

Applicants believe that the Examiner is using Applicant's disclosure as a blueprint to reconstruct the claimed invention from isolated pieces of the prior art contravenes the statutory mandate of § 103 which requires judging obviousness at the point in time when the invention was made. *See Grain Processing Corp. v. American Maize-Prods. Co.*, 840 F.2d 902, 907, 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988).

Accordingly, withdrawal of the rejections is respectfully requested.

**Paragraph 2 (Obviousness)**

The Examiner rejects Claims 28-29 under 35 U.S.C. 103(a) as obvious over Krebs (US Pat. No. 4,776,847) in view of Mower et al. (4,765,341).

The position of the Examiner can be found on pages 5-6 of the Office Action.

Applicants respectfully traverse for the same reasons as set forth in the previous paragraph and the following remarks.

Applicant's position regarding the Krebs reference can be found in the previous paragraph.

The '341 reference shows an implantable cardiac electrode for defibrillation. Therefore, this reference cannot give any teaching **for the electrical connection of a cannula tube**.

Claims 28 and 29 are directed to a special way of contacting the electrically conductive tube of the cannula with the stimulating wire. Because electrically conductive soldering of steel is difficult, the contact is formed according to claims 28 and 29.

Furthermore, the Krebs reference does not have any technological motivation to include a special way of contacting the electrically conductive tube of the cannula with the stimulating wire (hollow tube). The steel tube is located inside the hollow plastic tube; thus, it will be very difficult to add a connector according to Claim 28 to the steel tube because of the space limitation between the steel tube and the plastic tube.

In addition, Applicants note that Claims 28 and 29 depend on Claim 27, thus these claims are novel in view of their dependency with novel Claim 27.

Accordingly, withdrawal of the rejections is respectfully requested.

**Paragraph 3 (Obviousness)**

The Examiner rejects Claims 36-37 and 40 under 35 U.S.C. 103(a) as obvious over Krebs (US Pat. No. 4,776,847) in view of Haindl (4,889,529).

The position of the Examiner can be found on page 6 of the Office Action.

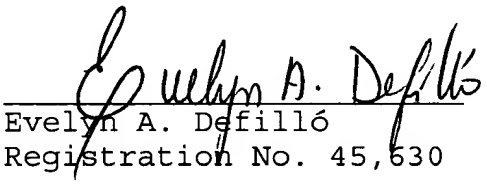
Applicants respectfully traverse for the same reasons as set forth in paragraph 1 and the following remarks:

Applicants note that these claims depend on Claim 27, thus these claims are novel in view of their dependency with novel Claim 27.

Accordingly, withdrawal of the rejections is respectfully requested.

Favorable consideration and early issuance of the Notice of Allowance is respectfully requested. **The Examiner is respectfully requested to contact the undersigned so that a telephonic interview may be arranged.**

Respectfully submitted,



Evelyn A. Defilló
Registration No. 45,630

PENDORF & CUTLIFF
5111 Memorial Highway
Tampa, Florida 33634-7356
(813) 886-6085

Date: **March 15, 2005**

**CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE**

I hereby certify that a copy of the foregoing AMENDMENT G for U.S. Application No. 09/438,759 filed November 11, 1999, was deposited in first class U.S. mail, with sufficient postage, addressed to: **Mail Stop AF,** Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on **March 15, 2005.**

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

Evelyn A. Defillo